

**REMARKS**

Claims 123-192 are pending in this application; claims 1-122 were previously canceled. By this Amendment, Applicant requests entry of the amendments of claims 123, 142, 143, and 159. The amendments of the claims above are provided solely to expedite prosecution of the present application and do not constitute an acquiescence to any reference identified by the Examiner. Particularly, the amendments presented herewith incorporate the suggestions provided by the Examiner, as well correct as antecedent basis issues. Support for these amendments can be found throughout the present application and in particular in the originally filed specification and drawings (see, for example, FIGS. 76A-76D and associated paragraphs [0297]-[0299]). Thus, no new matter is introduced by these amendments.

Applicant respectfully requests reconsideration of the claims in view of the amendments to the claims above, and the following remarks.

**Interview Summary**

Applicant acknowledges with appreciation the courtesy extended by the Examiner during the interview at the U.S. Patent and Trademark Office with the Applicant's attorneys on October 14, 2008. In accordance with MPEP § 713.04, Applicant summarizes herewith the details of the interview with the Examiner.

During the interview, Applicant's attorneys provided an overview of conventional stabilization systems and techniques. Additionally, Applicant's attorneys reviewed in detail a commercial product related to the claims of the present application, including viewing a video demonstration of the product and related procedure. Applicant's attorneys also presented a demonstration unit of the commercial product at the interview for review by the Examiner. Applicant's attorneys and the Examiner discussed in detail the subject matter of the pending claims of the present application, with particular attention directed to the subject matter of independent claims 123, 142, and 159 in comparison with that of the prior art cited in the Final Office Action. For example, it was noted that the prior art does not disclose, alone or in combination, a system comprising, among other things, a bone screw assembly having a slot to

receive a rod, and a sleeve detachably couples to the bone screw assembly. The Examiner suggested the related language in the independent claims appeared to be functional, and therefore suggested that the dimension of the rod relative to the slot be recited. The Examiner indicated that such an amendment would place the application in condition for allowance. The Examiner agreed to consider the amendments towards allowance after formal submission in an After Final Amendment.

Accordingly, and as noted below, Applicant presents the amendments suggested by the Examiner for independent claims 123, 142, and 159.

#### Claim Rejections

##### *35 U.S.C § 112, second paragraph*

In the Final Office Action, the Examiner indicates that claim 142, line 24 recites the limitation “the first closure member” with insufficient antecedent basis. Accordingly, claim 142, as well as claims 123 and 143, are amended to correct minor antecedent basis issues. Therefore, Applicant respectfully requests that the rejection of claim 142 under 35 U.S.C. § 112, second paragraph, be withdrawn.

#### Claim Rejections

##### *35 U.S.C 103(a)*

In the Office Action, claims 123-127, 130-135, 141-145, 148-153, 159-164, 167-172, and 178-192 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Number 6,251,112 to Jackson (“Jackson”). Further, claims 128, 129, 146, 147, 165, and 166 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Jackson in view of U.S. Patent No. 6,139,493 to Koros (“Koros”). Additionally, claims 136-140, 154-158, and 173-177 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Jackson in view of U.S. Patent No. 6,090,113 to Le Couedic (“Le Couedic”). Applicant respectfully traverses these rejections, and submits that none of the references cited, taken alone or in combination, discloses or suggests the systems as claimed.

Independent claims 123 and 159 each recite a system including, among other things, first and second bone screws configured to be screwed into first and second vertebrae, respectively, a first collar having a first slot and a second collar having a second slot, wherein the first and second collars are rotatably coupled to respective first and second bone screws. Independent claim 142 recites a system including, among other things, first and second bone screws, having first and second slots, respectively. Claims 123, 142, and 159 each further recites a first sleeve having a length longer than the first bone screw and a first channel formed in an opening of the sleeve wall, wherein the distal end of the first sleeve detachably couples to the first collar or bone screw with the first channel aligned with the first slot. Independent claims 123, 142, and 159 each further recites a rod to be received within the first slot, wherein after the rod and first bone screw are implanted, the sleeve is decoupled therefrom. By this Amendment, and pursuant to the suggestions of the Examiner, claims 123, 142, and 159 further recite the first slot having a slot width, and the rod having a width less than the slot width.

To reject claims in an application under Section 103, the Examiner must establish a *prima facie* case of obviousness. Using the Supreme Court's guidelines enunciated in *Graham v. John Deere*, 383 U.S. 1, 17 (1966), one determines "obviousness" as follows:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

In *KSR Int'l Co. v. Teleflex Inc.*, No. 04-1350 (U.S. April 30, 2007), the Supreme Court reaffirmed the Graham test, and indicated that although it should not be rigidly applied, a helpful insight into determining obviousness is to consider whether there is a teaching, suggestion or motivation in the prior art that would lead one of ordinary skill in the art to combine known elements of the prior art to arrive at the claimed invention. Importantly, the Court emphasized that a patent examiner's analysis under Section 103 should be made explicit in order to facilitate review.

Thus, to establish a *prima facie* case of obviousness, the Examiner has an obligation to construe the scope of the prior art, identify the differences between the claims and the prior art, and determine the level of skill in the pertinent art at the time of the invention. The Examiner must then provide an explicit, cogent reason based on the foregoing why it would be obvious to modify the prior art to arrive at the claimed invention. Applicant respectfully submits that the Examiner does not fulfill the obligation required to establish a *prima facie* case of obviousness.

Applicant respectfully submits that it would not have been known or obvious to modify the bone screw of Jackson as suggested in the Final Office Action, to include each and every feature of the system as claimed. Furthermore, even if all of the claim features were disclosed or suggested in the cited prior art, there is still no suggestion or indication that modifying the references would yield predictable results in accordance with *KSR International Co. v. Teleflex Inc.*, 127 U.S. 1727, L.Ed.2d 705.

For example, and as recognized by the Examiner, Applicant respectfully submits that none of the prior art of record, alone or in combination, discloses or suggests a system having, among other things, a first bone screw with a first slot having a slot width, a rod having a width less than the slot width, and a sleeve to be decoupled after the first bone screw and rod are implanted.

At least for the reasons recognized by the Examiner during the interview, Applicant respectfully submits that independent claims 123, 142, and 159 as amended are therefore allowable over the prior art of record.

Further, claims 124-141, 143-158, and 160-192 are also allowable at least for depending therefrom. Moreover, dependent claims 124-141, 143-158, and 160-192 are further allowable for reciting additional features not disclosed by the prior art relied upon by the Examiner. For example, claims 124, 143, and 160 recite the additional feature of the second sleeve comprising a second channel formed in an opening in a side wall. Claims 125 and 162 recite the additional feature of the first closure member being threaded for threaded engagement with the first collar. Claims 126, 144, and 163 recite the additional feature of the rod being curved for complementary curvature of the spine. Claims 127, 145, and 164 recite the additional feature of the first channel

extending a full length of the first sleeve. Claims 128, 146, and 165 recite the additional feature of the first sleeve including two first channels. Claims 129, 147, and 166 recite the additional features of the two first channels being on opposite ends of the first sleeve's longitudinal axis. Claims 130, 148, and 167 recite the additional feature that the first channel is a linear opening parallel to the longitudinal axis of the sleeve. Claims 131, 132, 149, 150, 168, and 169 recite the additional feature of the first channel comprising a non-linear shape. Claims 133, and 170 recite the additional feature of the first collar including a notch. Claim 151 recites the additional feature of the first bone screw including a notch. Claims 134, 152, and 171 recite the additional feature of the first sleeve including a passage. Claims 135, 153, and 172 recite the additional feature of the passage sized to permit passage of a tool. Claims 136-140, 154-158, and 173-177 recite the additional feature of a frame configured to engage the first and second sleeves for achieving distraction, translation, or compression. Claims 141 and 183 recite the additional feature of the first bone screw being cannulated. Claims 178-182 recite additional features of the bone fastener configuration. Claim 184 recites the additional feature of the detachably coupling including engaging a flange on the first sleeve with a flange on the first collar. Claims 185, 188, and 191 recite the additional feature of the rod being dumbbell-shaped. Claims 186, 189, and 192 recite the additional feature of detachably coupling inhibiting translational motion of the sleeve relative to the collar. Claims 187 and 190 recite the additional feature of detachably coupling including engaging a flange on the sleeve with a flange on the bone screw. Applicant respectfully submits that none of the prior art references cited, taken alone or in combination disclose or suggest the features of the dependent claims as recited in combination with the corresponding independent claim. Therefore, Applicant respectfully requests that the rejections of dependent claims 124-141, 143-158, and 160-192 also be withdrawn, and that claims 123-192 be passed to timely allowance.

### **CONCLUSION**

On the basis of the foregoing Remarks, Applicant submits that this Amendment After Final does not raise new issues for consideration or necessitate the undertaking of any additional

search of the art by the Examiner. This Amendment After Final should therefore allow for immediate action by the Examiner.

Applicant also submits that entry of this Amendment After Final and the accompanying remarks would place the present application in better form for appeal, should the Examiner dispute the patentability of any of the pending claims.

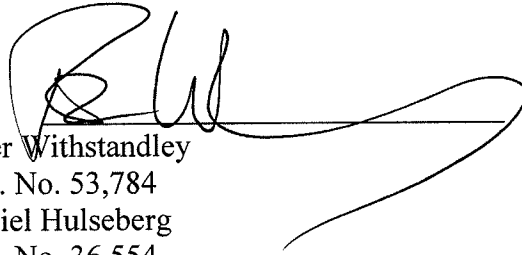
On the basis of the foregoing Remarks, Applicant respectfully submits that the pending claims of the present application are allowable over the prior art of record. Applicant thus respectfully requests that this Amendment After Final be entered by the Examiner and the rejections of the pending claims be withdrawn.

The Examiner is invited to contact the undersigned at (212) 408-2500 if any additional information or assistance is required.

Applicant authorizes the Commissioner to charge any fees (including fees for extra claims) and/or credit any overpayments associated with this paper to Baker Botts L.L.P. Deposit Account No. 02-4377, Ref. No. 003168.0577. Further, if a fee is required for an extension of time under 37 C.F.R. § 1.136 not provided for above, Applicant requests such extension and authorizes the charging of the extension fee to Baker Botts L.L.P. Deposit Account No. 02-4377, Ref. No. 003168.0577.

Respectfully submitted,

Dated: 10/24/2008

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